IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,	)	
	)	
	)	C.A. No. 05-590-GMS
Plaintiff,	)	
	)	
v.	)	
	)	
DEXCOM, INC.,	)	
	)	
	)	
Defendant.	)	

DEXCOM, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT OF ABBOTT DIABETES CARE, INC.

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Dated: August 31, 2005
160961.1

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Statutes and Regulations

Other Authorities

NATURE AND STAGE OF PROCEEDINGS

On August 11, 2005, Alameda, California-based Abbott Diabetes Care, Inc. ("Abbott") filed its Complaint against San Diego-based DexCom, Inc. ("DexCom"). Count I of the Complaint seeks a declaratory judgment that DexCom's yet-to-be-FDA-approved continuous glucose monitoring system for people with diabetes will infringe unspecified claims of four patents Abbott recently acquired. Count II alleges that DexCom's display at two diabetes-related scientific conferences infringes those same patents. Because Abbott's Complaint is premature, and because DexCom's attendance at the two scientific conferences cannot constitute acts of infringement pursuant to 35 U.S.C. § 271(e)(1), DexCom now moves to dismiss.

SUMMARY OF ARGUMENT

1. Because DexCom's STS system has not been approved by the FDA, may never be approved, and even if approved, may not be approved in its current form, Abbott's complaint for patent infringement is premature. The Court should decline to exercise jurisdiction and should dismiss Count I of Abbott's Complaint ("Declaration of Patent Infringement") for lack of subject matter jurisdiction pursuant to Fed.R.Civ.P. 12(b)(1).

2. All of DexCom's alleged conduct underlying Abbott's Complaint is exempt from infringement liability under title 35 of the United States Code and binding Federal Circuit precedent. "[U]ses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of

drugs" cannot constitute acts of infringement. 35 U.S.C. § 271(e)(1).[1] Count II of Abbott's Complaint ("Patent Infringement In Connection With Trade Shows") therefore fails to state a claim upon which relief can be granted, and should be dismissed pursuant to Fed.R.Civ.P. 12(b)(6).

INTRODUCTION

For millions of Americans who live with diabetes, one task remains a constant fixture in their daily routines: puncturing one of their fingers several times a day with a lancet. DexCom has been working for years to replace that prevalent—and painful—method of measuring blood glucose levels. By developing *continuous* blood glucose monitors—using tiny sensors inserted under a patient's skin which then transmit data to a small receiver—DexCom seeks to improve the quality of life for millions of people with diabetes. In March of 2005, DexCom filed an application with the Food and Drug Administration for Pre-Market Approval of its "STS" system. DexCom's goal, however, is not yet a reality. The FDA review process is ongoing, and when the FDA will make its decision, and what the outcome will be, are unknown.

On August 11, 2005, Alameda, California-based Abbott filed a Complaint seeking a declaratory judgment that DexCom's yet-to-be-FDA-approved device infringes numerous, unspecified claims of four patents which Abbott recently acquired. DexCom is working hard to gain approval, but there is no guarantee (1) that the FDA will approve the STS system, (2) when any approval would occur, or (3) that the STS system will not be modified prior to gaining FDA approval. Since FDA approval (if it comes at all) of

[1] The Supreme Court has held that this provision also applies to medical devices which are subject to FDA approval, like the glucose monitors here. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 673-74 (1990).

DexCom's STS system may be many months, or even years, down the road, Abbott's suit is premature. Count I of Abbott's Complaint should be dismissed pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure.

Abbott also alleges that DexCom's display of its STS system at two diabetes-related scientific conferences constitutes infringement of its acquired patents. DexCom's alleged display of the STS system at those two conferences falls within the statutory exemption from infringement liability under 35 U.S.C. § 271(e)(1), as interpreted by controlling Federal Circuit precedent. *See, e.g., Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992). Count II should therefore be dismissed because the facts alleged in the Complaint fail to state a claim upon which relief can be granted.

STATEMENT OF FACTS

At least 13 million Americans live with diabetes, and that number is expected to increase by nearly 1.3 million people each year. Worldwide, approximately 171 million people suffer from this chronic, life-threatening disease for which there is no known cure. DexCom's Prospectus, filed on April 14, 2005 at p. 1, attached as Exhibit B to the Request for Judicial Notice ("RJN") submitted herewith. Diabetes—the fifth leading cause of death by disease in the United States—is caused by the body's inability to produce or effectively utilize the hormone insulin, thereby preventing the body from adequately regulating blood glucose levels. Approximately 4.1 million Americans living with either Type 1 or Type 2 diabetes require insulin injections to regulate their blood glucose levels. *Id.* at 2.

Numerous factors—including the fat and carbohydrate content of meals, stress, exercise and illness—can cause blood glucose levels in a patient to fluctuate throughout the day. *Id.* Patients oftentimes are unaware of their fluctuating blood glucose levels.[2] Long-term complications related to diabetes include heart disease, loss of kidney function, blindness and the loss of limbs to amputation. *Id.* at 1. Patients also may experience short-term diabetes-related complications of varying severity. By closely monitoring and regulating blood glucose levels, people living with diabetes can reduce the frequency and severity of diabetes-related complications. Currently, the most prevalent form of glucose monitoring involves the use of "single-point finger stick devices." *Id.* at 2. To use these devices, a patient typically extracts a sample of her own blood by "sticking" her finger, places a drop of her blood on a test strip, and inserts that test strip into a glucose meter. The glucose meter then yields a reading that reflects her blood glucose level for the point in time at which she drew her blood.

For those patients who regularly monitor their blood glucose levels using this method, there are numerous drawbacks. The single-point finger stick devices can be difficult to use, and the process may be inconvenient, time-consuming, and of course, painful. *Id.* at 2-3. Moreover, even for a patient who tests his blood glucose level several times in a given day, the data generated—the information he obtains to manage his disease—is necessarily limited. Because the single-point finger stick devices provide the patient with his blood glucose level for that one moment in time (i.e., when he stuck his finger and drew his blood), he is unable to determine the trend or direction of his blood

[2] When a patient's blood glucose levels are too high, that condition is known as hyperglycemia. When a patient's blood glucose levels are too low, that condition is known as hypoglycemia.

glucose levels. *Id.* at 3. Without information to determine whether his blood glucose level is rising, falling or holding steady, the patient's ability to manage and maintain a normal blood glucose level is limited—which can be dangerous if, for example, he assumes an incorrect trend and treats himself accordingly. *Id.*

Due in part to the limited effectiveness of current blood glucose monitoring technology, the health care costs associated with diabetes care in the United States are high. According to the American Diabetes Association ("ADA"), the direct medical costs and indirect expenditures attributable to diabetes in 2002 in the United States were $132 billion. *Id.* at 2. Approximately $23 billion were spent in 2002 alone for *diabetes care* in the United States. *Id.* The worldwide market for single-point finger stick glucose monitoring systems (inclusive of the disposable test strips and finger lancets) was approximately $5.1 billion in 2003, and is expected to grow at a rate of nearly 12% to an estimated $8.9 billion in 2008. *Id.* Four companies—Roche Diagnostics, Johnson & Johnson, Bayer Corporation, and Abbott—currently account for substantially all of the glucose monitoring market that centers on single-point finger stick testing systems. *Id.* at 10.

DexCom was founded in 1999 to address the limitations and drawbacks of existing single-point finger stick glucose monitoring technology. DexCom is a "development stage" medical device company focused on the development of *continuous* glucose monitoring systems for people with diabetes. *Id.* at 1. DexCom is developing blood glucose monitoring systems that will continuously measure a patient's blood glucose level and transmit that information to a small cell phone-sized receiver. *Id.* at 3. DexCom's short-term and long-term continuous glucose monitors, if approved by the

FDA, would eliminate many of the drawbacks associated with single-point finger stick systems. DexCom's technology utilizes a subcutaneous device—a small sensor inserted under the patient's skin—which continuously tests glucose levels and wirelessly transmits that data to a small receiver. DexCom's glucose monitors would eliminate much of the pain and inconvenience associated with finger sticking, and would provide "real-time" data—including one, three, and nine-hour trends—to ensure that patients can effectively monitor and manage their glucose levels. *Id.* at 3.[3]

In March of 2005, DexCom filed an application with the FDA for pre-market approval ("PMA") of its short-term continuous glucose monitoring system ("STS"). Pre-market approval is the FDA process of scientific and regulatory review to evaluate the safety and efficacy of medical devices such as DexCom's STS. As part of that process, DexCom is required to conduct clinical trials to demonstrate the effectiveness and safety of its devices. *Id.* at 1, 11, 29. DexCom, as the sponsor of clinical trials on its STS system, must recruit qualified, interested physicians to serve as clinical investigators. The clinical investigators, using prototypes of the STS system, are responsible in turn for enrolling patients in clinical trials using the device. 21 C.F.R. § 812.40 ("Sponsors are responsible for selecting qualified investigators and providing them with information they need to conduct the investigation properly."). The data collected from those clinical trials is submitted to the FDA as part of the PMA process. FDA regulations impose strict controls on the devices under clinical investigation, limiting distribution "only to

[3] DexCom is developing two types of continuous glucose monitoring systems: a short-term device and a long-term device. In the short-term device, the sensor is inserted by the patient. In the long-term devices, the sensor is implanted by a physician. The Complaint accuses only the short term device (STS) of infringing the four patents Abbott acquired recently.

qualified investigators participating in the investigation." 21 C.F.R. § 812.43 (b). Sponsors of clinical trials (here, DexCom), must obtain a signed commitment from each clinical investigator agreeing to be bound by governing FDA regulations. 21 C.F.R. § 812.43(c)(4)(i).

Even after data from the initial clinical trials has been submitted to the FDA, the FDA can require—as part of the review and approval process—that DexCom submit additional data to demonstrate the safety and/or effectiveness of the STS system. *See, e.g.,* 21 C.F.R. § 812.30(b)(3) (noting that FDA may disapprove an application if "the sponsor fails to respond to a request for additional information within the time prescribed by FDA"). In disclosures recently filed with the SEC, DexCom acknowledged that, "the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials." DexCom's Form 10-Q (Quarterly Report) filed with the SEC on August 2, 2005 (RJN Ex. C) at p. 17. DexCom, like Abbott and other similarly situated companies,[4] attends scientific conferences at which it exposes its proposed product to physicians who may participate in clinical studies. As part of that effort, DexCom has attended and displayed its STS system at diabetes-related scientific conferences. Complaint at ¶ 16. At these conferences, DexCom is prohibited by FDA regulations from engaging in sales

[4] Abbott attended the June 2005 American Diabetes Association conference in San Diego, California, and the August 2005 American Association of Diabetes Educators conference, at which it displayed its own Freestyle Navigator Glucose System, which is still under FDA review. See American Diabetes Association listing of June 2005 conference exhibitors (RJN Ex F) and American Association of Diabetes Educators list of August 2005 annual conference attendees (RJN Ex. G).

and marketing of its pre-approval STS system. *See* 21 C.F.R. § 812.7. Abbott, like DexCom, displayed its Navigator Continuous Glucose Monitoring System at the conferences, although it is also under FDA review and has not yet received approval.

To date, DexCom has not received approval from the FDA to market its STS system. On August 2, 2005, DexCom disclosed to the SEC and its investors that "we do not expect to be able to commercialize our short-term continuous glucose monitoring system or long-term continuous glucose monitoring system before 2006 and 2007, respectively." RJN Ex. C at 15. DexCom also acknowledged that approval by the FDA "generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA" and that "there is no guarantee that the PMA application we submitted in March 2005 for our short-term continuous glucose monitoring system will result in any approval of the system by the FDA." *Id.* In July of 2005, the FDA verbally notified DexCom that it would be receiving a "Major Deficiency Letter" requesting that DexCom submit additional information to the FDA as part of the review of the PMA application for the STS system. *Id.* Even if the FDA approves DexCom's PMA application for the STS system, that approval may be conditioned on changes being made to the system.

In April of 2004, Abbott acquired Alameda, California-based TheraSense, Inc. for $1.2 billion. Abbott Laboratories, Inc.'s Form 10-Q, filed with the SEC on August 3, 2005 (RJN Ex. D) at p. 9. TheraSense was another company developing a continuous glucose monitoring system to replace existing single-point finger stick glucose monitoring technology dominated by Roche, Johnson & Johnson, Bayer and Abbott. As part of its acquisition of TheraSense, Abbott acquired the four patents it has asserted

against DexCom in this case. *See* Complaint at ¶¶ 8-11. Abbott also acquired TheraSense's non-FDA-approved continuous glucose monitor prototype, the "Freestyle Navigator Glucose System." RJN Ex. C at 16.

Abbott knows from its acquisition of TheraSense that FDA approval for continuous glucose monitoring technologies has been highly uncertain. TheraSense filed a PMA in November of 2003 for a continuous glucose monitor—after having conducted what it thought to be successful clinical trials—only to announce over a year later that additional clinical trials would be required before FDA approval. To date, Abbott has still not received FDA approval for its continuous glucose monitoring products. TheraSense, Inc.'s Form 10-K Filed March 12, 2004 (RJN Ex. E) at pp. 30, 31 ("We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. Development of Navigator and other products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products.").

On August 1, 2005, Abbott sent a letter to the CEO of DexCom asserting that unspecified claims of Abbott's four patents cover DexCom's STS system, and stating that Abbott "will take every reasonable step to enforce" those patents. Complaint at ¶19. The letter failed to provide any analysis or rationale underlying Abbott's allegations that DexCom's STS system will infringe those patents. On August 11, 2005, Abbott filed its Complaint, which DexCom now moves to dismiss.

ARGUMENT

I. THE COURT SHOULD DISMISS COUNT I OF ABBOTT'S COMPLAINT AS PREMATURE.

This Court has discretion to refuse to hear an action brought under the Declaratory Judgment Act, 28 U.S.C. § 2201.[5] *See Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995) (exercise of that discretion involves "considerations of practicality and wise judicial administration."). The burden is on Abbott, as the party invoking 28 U.S.C. §2201, to persuade the Court to exercise jurisdiction. *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.,* 363 F.3d 1361, 1373 (Fed. Cir. 2004); *Erbamont, Inc. v. Cetus Corp.*, 720 F. Supp. 387, 391 (D.Del. 1989).[6] In determining whether a patent holder's complaint under 28 U.S.C. § 2201 satisfies the Article III case-or-controversy requirement, the Federal Circuit requires that a defendant engage in "present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Sierra Applied Scis.,* 363 F.3d at 1373, quoting *BP Chems. Ltd. v. Union Carbide Corp.,* 4 F.3d 975, 978 (Fed. Cir. 1993). That determination is made from facts as they existed at the time Abbott filed its Complaint—August 11, 2005. *Lang v. Pacific Marine & Supply Co., Ltd.,* 895 F.2d 761, 764 (Fed. Cir. 1990). Because there currently is no "accused device" to compare against the claims of Abbott's four patents—and because it is unclear whether or when such a device will exist—Abbott's request for a declaration of infringement should be dismissed.

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[5] 28 U.S.C. § 2201 provides that "in a case of actual controversy" a court may "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

[6] Where the defendant has challenged jurisdictional facts, the court may receive evidence to resolve the jurisdictional factual dispute. *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 281 (E.D. Pa. 1994).

In Count I of its Complaint, Abbott seeks a "judicial declaration that DexCom's product *will infringe* one or more claims of each of Abbott's patents." Complaint at ¶ 25 (emphasis added). The issue of *future* infringement, however, is not ripe for adjudication. *See Telectronics,* 982 F.2d at 1527. In *Telectronics*, the patentee (Telectronics) filed a complaint against Ventritex before Ventritex's implantable defibrillator had received FDA approval. Ventritex moved to dismiss on the grounds that the declaratory judgment claim sought an advisory opinion. The district court granted defendant's motion, declining to exercise jurisdiction under 28 U.S.C. § 2201, and the Federal Circuit affirmed, stating that the district court "could have correctly ruled that the case lacked sufficient immediacy and reality to meet the actual controversy requirement" because defendant's device was undergoing FDA review and "was years away from potential FDA approval." *Id.*[7] The Federal Circuit also emphasized that "[t]here was no certainty that the device when approved would be the same device that began clinical trials." *Id.; see also Lang*, 895 F.2d at 764 (plaintiff failed to meet actual controversy requirement since accused infringer's ship hull would not be finished until at least nine months after complaint was filed); *NeoRX Corp. v. Immunomedics, Inc.,* 877 F. Supp. 202, 214 (D. N.J. 1994) (finding that patentee failed to make a sufficient allegation of immediacy and reality because it was unclear whether FDA would grant defendant's application for license to manufacture accused product); *Abbott Labs., Inc. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) (dismissing Abbott's declaratory judgment claim where FDA approval for defendant's drug had not been granted at time

[7] The Federal Circuit also noted that, even if "the district court believed that an actual controversy existed, the district court's decision could have been an exercise of its discretion not to decide the declaratory issues at this early stage." *Id.*

Abbott filed complaint and no guarantee that approval would come at any particular date in future).

Like Ventritex's accused implantable defibrillator in *Telectronics*, DexCom's device has not received approval from the FDA, and it cannot be marketed or sold in the United States. *See* 21 C.F.R. § 812.7. In fact, there is no guarantee that the FDA will ever approve DexCom's STS system, and FDA approval (if given) may be years down the road. DexCom's own public statements to the SEC and its investors caution that "we do not expect to be able to commercialize our short-term continuous glucose monitoring system or long-term continuous glucose monitoring system before 2006 and 2007, respectively." RJN Ex. C at 15 (further noting that approval by the FDA "generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA" and that "there is no guarantee that the PMA application we submitted in March 2005 for our short-term continuous glucose monitoring system will result in any approval of the system by the FDA.").

Even if the FDA does approve the STS system, it can require that DexCom make changes to the device as a condition of approval. *See, e.g.,* 21 C.F.R. § 814.45 (specifying multiple grounds for FDA denial of a PMA application). And if the FDA approves the current STS device without requiring changes, DexCom may voluntarily modify the device prior to marketing it as a result of information learned from its ongoing research and development efforts. Abbott's claim for future infringement therefore is not ripe for adjudication. Given the uncertain timing and outcome of the FDA's review of DexCom's STS system, "it is not at all clear that we will ever have a case and controversy

between these litigants that arises under federal patent law." *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1289 (N.D. Cal. 1991).

In *Intermedics*, the district court declined to exercise jurisdiction under 28 U.S.C. § 2201 in another case brought against Ventritex and its implantable defibrillator (pending review by the FDA at the time of plaintiff's complaint). The district court granted Ventritex's motion to dismiss plaintiff's declaratory relief claim, focusing on the fact that the FDA's approval was not guaranteed, and that the timing of the potential approval was uncertain. The court also noted that the accused device could be modified as a condition of FDA approval, thus changing "the content of the dispute between these parties." 775 F. Supp. at 1290. The court concluded that, because defendant's activities *at the time of the complaint* were protected under 35 U.S.C. § 271(e)(1), "plaintiff is not suffering, at this juncture, any legally cognizable harm as a result of defendant's conduct." *Id.* The court found "no compelling reason to assert jurisdiction to determine whether defendant's product, *as currently configured,* infringes plaintiff's patent rights." *Id.* The Federal Circuit affirmed. 991 F.2d 808 (Fed. Cir. 1993).

Because FDA review of DexCom's STS glucose monitoring system is ongoing and the outcome uncertain, there is no "accused product" for the Court to compare against the construed claims of the four Abbott patents. Abbott's declaratory judgment claim is premature. The Court lacks subject matter jurisdiction, and Count I should be dismissed pursuant to Fed.R.Civ.P. 12(b)(1). Alternatively, if the Court determines that an actual controversy exists, there is no compelling reason to exercise jurisdiction at this stage of the FDA review process. *See, e.g., Intermedics,* 775 F. Supp. at 1290.

II. COUNT II FAILS TO STATE A CLAIM FOR WHICH RELIEF CAN BE GRANTED BECAUSE DEXCOM'S DISPLAY AT TWO SCIENTIFIC CONFERENCES IS EXEMPT UNDER 35 U.S.C. § 271(E)(1).

Abbott also claims that DexCom's actual conduct, as of the August 11, 2005 date of the Complaint, infringes the four Abbott patents. Specifically, Abbott alleges that DexCom has attended two diabetes-related "trade shows where it has publicized and displayed its products." Complaint at ¶ 16. The Federal Circuit addressed this exact issue in *Telectronics*, 982 F.2d 1520. In *Telectronics,* the Federal Circuit held that attendance at such scientific conferences was exempt under 35 U.S.C. § 271(e)(1). *Id.* at 1523. *Telectronics* is on "all fours" with the facts of this case, and its outcome controls here.

In *Telectronics*, defendant Ventritex was conducting clinical trials on its implantable defibrillator as part of the FDA review process. During the clinical trials, Ventritex displayed and demonstrated its defibrillator at seven medical conferences, including conferences where non-physicians were present. In communicating with investors and the media, Ventritex's CEO provided updates on the status of the clinical trials, stating that early clinical results were promising. Telectronics filed a complaint seeking declaratory relief, alleging that Ventritex's actions at the seven scientific conferences were not exempt under Section 271(e)(1). The only *conduct* (i.e., making, using or selling) that Telectronics alleged was "unrelated to FDA approval," and therefore outside of the protections of Section 271(e)(1), was "Ventritex's demonstration of its defibrillator to some non-physicians at medical conferences." *Id.* Ventritex moved to dismiss, and the district court found that the alleged infringing conduct (i.e., demonstrations to non-physicians at trade shows) was exempt under 35 U.S.C. §

271(e)(1). The Federal Circuit affirmed, holding that "such demonstrations constitute an exempt use reasonably related to FDA approval." *Id.* at 1523.

DexCom's alleged actions at scientific conferences are likewise exempt under Section 271(e)(1). Although DexCom (like Ventritex) has submitted data from its initial clinical trials, the FDA can require DexCom to submit additional data to demonstrate the safety and/or effectiveness of its STS system. *See* RJN Ex. C at 17 ("the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, *or may require us to pursue additional pre-clinical studies and clinical trials*.") (emphasis added). The FDA permits "sponsors of clinical investigations to continue to enroll subjects [in clinical trials] at a pre-determined rate while a marketing application is being . . . reviewed by the Office." FDA Memorandum #D96-1, entitled "Continued Access to Investigational Devices During PMA Preparation and Review," dated July 15, 1996 (RJN Ex. H) at p. 2. The FDA recognizes that "[s]uch a policy is scientifically sound as it allows the sponsors to collect additional safety and effectiveness data in support of the marketing application or to address new questions regarding the investigational device during this intervening period." *Id.*

Because the FDA may require additional clinical data to support DexCom's claim that the STS system is safe and effective, DexCom must continue to expose the STS system to qualified and interested physicians who could serve as participants in future clinical studies. If DexCom were to assume approval and wait until after the FDA makes a request for further data before introducing its device to potential clinical investigators, the PMA review process could be delayed indefinitely. In preparing for possible

additional clinical trials, DexCom has attended and displayed its STS system at diabetes-related scientific conferences. Complaint at ¶ 16. Under the Federal Circuit's holding, those uses of the STS system are "reasonably related to FDA approval, because device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing." *Telectronics*, 982 F.2d at 1523.

Abbott's Complaint is nearly devoid of allegations, beyond boilerplate, supporting Count II, and what allegations are pled are weaker than those found insufficient in *Telectronics*. Unlike the plaintiff in *Telectronics*, Abbott does not allege that DexCom "demonstrated" its STS system, but rather, only that DexCom "displayed" it. *See* Complaint at ¶ 16-17. These allegations, pled "upon information and belief," are facially inadequate. Display of medical devices undergoing regulatory review at trade shows is "reasonably related" to gathering information for submission to the FDA, and, therefore, exempt from infringement under Section 271(e)(1). *Telectronics*, 982 F.2d at 1524; *see also Abtox, Inc. v. Exitron Corp.,* 122 F.3d 1019, 1030 (Fed. Cir. 1997) (Section 271(e)(1) "does not look to the underlying purposes or attendant consequences of the activity . . . , as long as the use is reasonably related to FDA approval."); *Nexell Therapeutics, Inc. v. Amcell Corp.,* 199 F. Supp. 2d 197, 205 (D. Del. 2002) (McKelvie, J.) ("In making this determination [under 271(e)(1)], considerable leeway must be given to the defendant, because 'it will not always be clear to parties setting out to seek FDA approval for their new product exactly what kinds of information, and in what quantities, it will take to win the agency's approval.'") (quoting *Intermedics*, at 775 F. Supp. at 1280.)

The FDA permits sponsors of investigational devices, like DexCom, to enroll physicians in its clinical investigations through the exact process DexCom followed here. According to the FDA's "Guidance to Industry and FDA Staff," any person "wishing to make known through a notice, publication, *display*, mailing, *exhibit*, announcement or oral presentation the availability of an investigational device *for the purpose of obtaining clinical investigators to participate in a clinical study*" should "announce the availability of the device at "scientific conferences whose . . . audience is comprised primarily of experts qualified by scientific training and experience to investigate the safety and effectiveness of devices." FDA Center for Devices and Radiological Health's Office of Compliance, *Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects,* dated March 19, 1999 (RJN Ex. I) at p. 1 (emphasis added).

As DexCom has acknowledged to its investors and to the public, and as Abbott has experienced, FDA review is an uncertain process. Because it is indisputable that new data from additional clinical trials may be required to secure approval from the FDA, Abbott's vague, conclusory allegation that DexCom purportedly manufactured the displayed device for "showcasing" is insufficient as a matter of law. *Abtox*, 122 F. 3d at 1027 (rejecting plaintiff's argument that "actual purpose of [defendant's] tests was not to secure approval, but was intended . . to promote the [device] to potential customers" and holding that defendant's activities fell within §271(e)(1) exemption).[8]

[8]Although not necessary to decide this motion, to assure the Court that DexCom has acted within 35 U.S.C. §271(e)(1), DexCom has filed a brief declaration from its Vice President of regulatory affairs.

CONCLUSION

In a patent case, the Court must compare the claims as construed against the defendant's accused device to determine questions of infringement. Here, it is unknown whether DexCom will ever have an FDA-approved short-term glucose monitoring system, or to what extent that device (if approved) will resemble the one currently under FDA review. Abbott's Complaint is premature, and the Court should dismiss Count I for lack of subject matter jurisdiction. DexCom's display of its STS system at scientific conferences is exempt from infringement under 35 U.S.C. § 271(e)(1). Count II of Abbott's Complaint therefore must be dismissed for failure to state a cause of action upon which relief can be granted.

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Dated: August 31, 2005
160961.1

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of August, 2005, the attached **DEXCOM, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT OF ABBOTT DIABETES CARE, INC.** was served upon the below-named counsel of record at the address and in the manner indicated:

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